## REMARKS

The Official Action dated January 29, 2004 has been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claims 1-10 have been amended for matters of clarity and form in accordance with customary U.S. patent practice. Claim 11 is added and includes a limitation previously set forth in claim 9. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

Claims 1-10 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner asserted that claim 1 is vague with respect to the placement of the time indicator and that claims 3, 4, 7 and 8 are vague and indefinite because they recite method steps or fabricating processes and do not clarify the device of claim 1.

This rejection is traversed and reconsideration is respectfully requested. Specifically, claim 1 recites that the time indicator is arranged in contact with the wicking member at a variable position between the upstream and downstream ends thereof, thereby permitting variation of the time elapsing from the application of liquid to the liquid application zone until the indicator substance or substance combination in the time indicator changes color. As is apparent from the specification, the limitation that the time indicator is arranged in contact with the wicking member at a variable position between the upstream and downstream ends thereof means that the time indicator can be arranged as desired along the length of the wicking member. Thus, in the present device, the time indicator provides a confirmation that liquid applied to the liquid application zone has been transported through

the detection zone to the wicking member and therefore that the assay is completed and the result may be read in the detection zone. The ability to vary the position of the time indicator between the upstream and downstream ends of the wicking member is important in that it allows the time elapsing from the liquid application to the indicator color change to be shortened or prolonged as desired and thus specifically selected for a particular assay. This is discussed in further detail in the specification at page 6, lines 10-22. As claim 1 clearly describes the variable position arrangement of the time indicator, claim 1 is definite to one of ordinary skill in the art.

With respect to claims 3, 4, 7 and 8, Applicants submit that these claims do not recite method steps but rather the physical arrangement of the time indicator in the assay device. To further emphasize the physical arrangement of the time indicator as recited in claims 3, 4 and 8, these claims have been amended to recite that the time indicator is "included on" the indicated element rather than "applied to" the indicated element. It is therefore submitted that claims 3, 4, 7 and 8 are definite to one of ordinary skill in the art.

Thus, claims 1-10 particularly point out and distinctly claim the subject matter which Applicants regard as the invention in accordance with the requirements of 35 U.S.C. §112, second paragraph. It is therefore submitted that the rejection has been overcome, and reconsideration is respectfully requested.

Claims 1-6 and 10 were rejected under 35 U.S.C. §102(b) as being anticipated by the May et al U.S. Patent No. 5,602,040. Claims 7-9 were rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over May et al. The Examiner asserted that May et al teach a device embodiment containing a control zone loaded with an antibody that will bind to a labeled antibody from a first zone or containing an anhydrous reagent that, when moistened, produces a color change or color formation. The

Examiner further asserted that May et al teach the use of an absorbent sink and that the time indicator taught by May et al is located directly on the wicking member or is located on the wicking member and the wicking member is disposed on a test strip.

However, Applicants submit that the assay devices and methods defined by claims 1-10 are neither anticipated by nor rendered obvious over May et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, according to claim 1, the assay device of the present invention comprises an elongate flow matrix, a wicking member and a time indicator. The elongate flow matrix allows lateral transport of fluid therethrough by capillary action and comprises a liquid application zone and a detection zone downstream of the liquid application zone. The detection zone has an immobilized capture agent capable of directly or indirectly binding to an analyte in an aqueous sample. The wicking member is at the downstream end of the flow matrix and has an upstream end and a downstream end. The time indicator is downstream of the detection zone for indicating when liquid applied in the liquid application zone has reached the time indicator. The time indicator comprises an indicator substance or substance combination which is capable of exhibiting a visible color change when hydrated by the aqueous sample. In accordance with an important feature, the time indicator is arranged in contact with the wicking member at a variable position between the upstream and downstream ends, thereby permitting variation of the time elapsing from the application of liquid to the liquid application zone until the indicator substance or substance combination changes color. Thus, the assay device is adaptable for use in different assays requiring different liquid travel times by placing the time indicator at a desired position between the upstream and downstream ends of the wicking member.

May et al disclose an analytical test device which, as described at column 5, beginning at line 8, may include a control zone to convey an unrelated signal to the user that the device has worked. May et al disclose that the control zone can be loaded with an antibody that will bind to the labeled antibody or may contain an anhydrous reagent that, when moistened, produces a color change or a color formation. Further, the control zone could contain immobilized analyte which will react with excess labeled reagent. However, Applicants find no teaching or suggestion by May et al that the control zone may be variably arranged downstream of a flow matrix or a detection zone. To the contrary, May et al teach away from such an assay device in the figures which show a relatively small control zone window 205 (Fig. 6), 509 (Fig. 8) and 604 (Fig. 11), without any teaching of means for viewing a time indicator placed anywhere other than at the relatively small window.

On the other hand, in the assay device of the present invention, wherein the time indicator is arranged in contact with the wicking member at a variable position between the upstream and downstream ends thereof, the time indicator has a wide range of positions along the wicking member. For example, with reference to Fig. 3, the position of the timer indicator 14 may be varied along the length of the wick 13 as desired depending on the particular assay which is to be conducted. Applicants find no teaching or suggestion by May et al in this regard.

Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference, *In re Robertson*, 49 U.S.P.Q.2d 1949, 1950 (Fed Cir. 1999). In view of the failure of May et al to teach a time indicator arranged in contact with a wicking member at a variable position, May et al do not disclose each and every element as set forth in the present claims. Thus, May et al do not anticipate the present claims under 35 U.S.C. §102.

Moreover, it is error to find obviousness where references diverge from and teach away from the invention at hand, *In re Fine*, 5 U.S.P.Q.2d 1596, 1599 (Fed. Cir. 1988). As May et al fail to teach or suggest varying the position of the control zone or any element therein, and rather teach a control zone at a set location, May et al teach away from the presently claimed assay device. Thus, May et al do not render the present claims obvious.

It is therefore submitted that the assay device and methods defined by claims 1-10 are neither anticipated by nor rendered obvious over May et al, whereby the rejections under 35 U.S.C. §§ 102 and/or 103 have been overcome. Reconsideration is respectfully requested.

Claims 1-5 and 10 were rejected under 35 U.S.C. §102(b) as being anticipated by the Kiser et al European reference EP 826 777. The Examiner asserted that the time it takes for the timer segment of Kiser to change color is determined by the temperature and by characteristics of the testing reagent, specifically inhibitor concentration, amount of glucose and hydration and oxygen diffusion rates.

However, Applicants submit that the assay devices and methods defined by claims 1-5 and 10 are not anticipated by Kiser et al and are patentably distinguishable therefrom. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

The assay device defined by claim 1 has been discussed in detail above. Kiser et al provide no teaching of such an assay device or the improvements provided thereby. More specifically, as discussed in the present specification at page 2, beginning at line 10, Kiser et al disclose a test strip having a chemical timer. The timer is a dry coating of an indicator, an enzyme-containing reagent that when hydrated can react with glucose to change the color of the indicator, and inhibitor to inhibit the changing color of the indicator, glucose, and optionally an aldose that does not react with the enzyme and the reagent. The time necessary for the timer color to change can be controlled by varying the inhibitor concentration. As

noted by the Examiner, the time period is also dependent on temperature, the amount of glucose, and the hydration and oxygen diffusion rates. As is apparent from the teachings of Kiser et al, for example at page 3, lines 44-47, the object of Kiser et al is to provide a visible indicator to avoid reading the test result too early, based primarily on the passage of a predetermined amount of time.

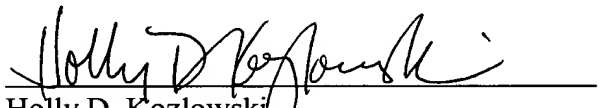
On the other hand, in the assay devices of the present invention, the object of the time indicator is to indicate when liquid applied in the liquid application zone has reached the time indicator, thereby indicating that the sample has successfully passed through the detection zone. Applicants find no teaching or suggestion by Kiser et al relating to an assay device wherein a timer indicator is arranged in contact with a wicking member downstream of a flow matrix containing a detection zone at a variable position between the upstream and downstream ends thereof. While the time period of Kiser et al may be varied by use of different concentrations of the various ingredients in the dry coating, and/or by the temperature at which a test is conducted, one skilled in the art will appreciate that such variations are labor intensive, either for the manufacturer or for the device user in the case of temperature variation. In contrast, the time elapsing between application of liquid to the liquid application zone and a color change by the indicator substance or substance combination in the present invention is easily varied by simply varying the position of the time indicator along the length of the wicking member. Applicants find no teaching or suggestion by Kiser et al of a time indicator which is arranged in contact with a wicking member at a variable position thereof between upstream and downstream ends.

In view of the deficiencies in the Kiser et al teachings, Kiser et al do not disclose each and every element as set forth in the present claims, and therefore do not anticipate the present claims under 35 U.S.C. §102 *In re Robertson, supra.* It is therefore submitted that the

assay devices defined by claims 1-5 and the method of performing an assay using such a device as defined by claim 10 are not anticipated by and are patentably distinguishable from Kiser et al, whereby the rejection under 35 U.S.C. §102 has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejections under 35 U.S.C. §§ 102, 103 and 112, second paragraph, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,



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